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One can conclude that pesticide laws and common law principles applicable to the use of pesticides do a reasonably adequate job of protecting the public. The development of further regulation by way of statutes and rules is necessary in some instances before adequate, useful and practical means are made available, thus minimizing pesticide accidents. Statutory control should not only regulate, restrict and likewise even make lawful certain acts and procedures, but also, pesticide laws should serve as educational tools to inform and delineate proper activities of users, sellers and applicators.

Statutes which merely prohibit, do serve a useful purpose. However, in the case of a law limiting activities of individuals, while the reasons for the limits may be obvious to law makers, this is not always the case with the affected or regulated parties. Statutory language, while not necessarily explanatory per se, should be detailed enough to point out the proper means of compliance.

The program for restricted use pesticides and certification of applications as established under the current law for registration of pesticides, including herbicides, has generally succeeded.

THE PHILOSOPHY OF HERBICIDE REGISTRATION

INTRODUCTION

When we speak of a toxic substance, we are speaking of any material which will inhibit or destroy the normal functions of living tissues when that tissue is exposed to a specific dosage for a specific duration. When we speak of a herbicide, however, we mean a specific chemical compound that has been tested and is used for its ability to kill and destroy the tissue of undesirable plants (weeds), generally in the presence of desirable plants, as an economic "good", a practical contribution to some part of the economy.

THE EFFECTS OF TOXIC SUBSTANCES

When the concentration of a toxic substance becomes high enough, through intentional or accidental release or assimulation, it may cause immediate (acute) effects. These effects have the benefit of facilitating the correlation of a specific toxic substance and its symptoms. More often, however, the toxic substance is present in low (but still active) concentrations, which may not cause symptoms to appear immediately. This is known as 'chronic' exposure, and the delay between exposure and the appearance of symptoms is called the latency period. The phenomena of chronic exposure and a latency period make it very difficult to correlate specific symptoms with specific chemicals. Extensive testing may be needed, in which the chemical is administered in what is judged to be an acute dose. The exact

mechanism of toxicity may be difficult or impossible to elucidate--either due to our lack of complete understanding of the chemical interactions of life, or due to the non-specific action of the toxic substance. (1,2,3,4).

TYPES OF TOXIC SUBSTANCES

Mutagens. These substances may cause random changes in the genetic material of nearly all living things. While cells possess systems for the correction of mutations once the mutation is complete the information is changed.

Carcinogens. These substances may cause the unrestricted proliferation of abnormal cells which we call cancer. Mechanisms seem to be mutagenic in some cases, but are largely unknown.

Teratogens. These substances may cause birth defects and abnormalities. The classic example is the sedative drug Thalidomide, which was identified as the causative agent in a number of similar deformed births. Thalidomide was subsequently shown to be teratogenic, carcinogenic and mutagenic.

General toxins. These substances may affect various life functions. A good example is mercury, which is known to react with the sulfhydril groups in proteins. These groups play a major role in the three-dimensional configuration of large protein molecules. The biochemical activities of these proteins are defined by their ability to recognize other molecules by their three-dimensional characteristics. Changes in the shape of the

protein may reduce or destroy that ability. General toxins may cause anything from discomfort, headaches and indigestion, to behavioral changes, neurological damage and/or death.

Chemicals which have the above effects on properties are not commonly approved for registration as herbicides by the Environmental Protection Agency. (6,7,8,9,10,11,12).

Scientific testing procedure is designed in such a way that false results are given with a certain frequency. Therefore the trade-off is between having tests sensitive enough to find small yet real differences and avoiding false positive results due to normal random variation in results.

WHAT LEVEL OF RISK IS ACCEPTABLE?

In the decision process to determine whether the use of a substance constitutes an unacceptable risk, traditional methods of cost/benefit analysis break down, because important parameters are not well known. For instance, there is a 'zero/infinity' paradigm, meaning that the probability of an event is near zero, but the potential cost of that event approaches infinity. Advanced technology can reduce the chance of this happening to near zero, but the potential cost remains high (and may even get higher, since an ever more costly piece of equipment is destroyed).

The presence of toxic substances in the ambient environment is a problem of our entire society. At present, however, small segments of the society are making the significant decisions (or lack of decisions) for the entire society. Scientists evaluate the effects of toxics, and may make recommendations regarding decisionmaking, but the actual power to make and enforce decisions rests with various government agencies.

The usual method of governmental decisionmaking is cost/benefit analysis. Costs and benefits of an action are estimated, and if the benefits exceed the costs, the action is carried out. This system sounds extremely simple, and it can be. Problems generally arise, however, because to facilitate comparison both costs and benefits must be translated into a common currency the arbitrary units of dollars and cents.

In the regulation of toxic substances, cost/benefit is reduced to the concept of "acceptable risk". Actuarials determine the level of risk which the population seems to accept (e.g. driving cars), and assumes that comparable environmental risks will be acceptable. One major flaw in this system is that there is a large data base for accurate estimation of the risks while driving a car, but little such data exists for the estimation of environmental and public health risks.

The other major weakness of this approach is that there is rarely an opportunity for the general public to express its views on the level of risk they are willing to accept. Ideally, a

well-informed public should be the primary decisionmaker in regard to the risks to which they will be exposed.

Assuming that these problems can be ironed out of the process, there remains a large problem in the validity of one of the primary assumptions of cost/benefit analysis. This is the assumption that relationships are continuous--meaning that a small change in the concentration allowed by regulation would cause only a small change in the costs of maintaining this level, and a corresponding small change in the benefits expected. This may not always be the case.

Chemical Description

One of the problems that people face when trying to help solve the toxics problem is the exotic jargon of chemists. Chemists are, of course, not the only group with their own jargon: lawyers, bureaucrats, psychologists, artists, carpenters, plumbers, and almost any other special interest group develop their own private channel to talk on by the use of specific words. In the final analysis they are all the same; a carpenter speaks of headers, liners, jacks and sills, while a chemist talks about carbon chains, hydroxyl groups, benzene rings and inorganic salts. There are many chemicals with names; and to make matters worse, there is often more than one name for the same chemical.

Everything is composed of **atoms**, and an atom is mostly empty space. Each atom has a small heavy core **(nucleus)** made of **Protons** and **neutrons.** A number of light **electrons** are in

orbits around the nucleus. The protons in the nucleus have a positive charge, and the electrons have a negative charge (neutrons have no charge). If an atom has as many electrons as protons, the atom has no net charge as a whole. If there is a shortage or surplus of electrons, the atom will have a net charge, and may be called an **ion** (say eye-on). The condition of the electrons determines the chemical properties of an atom - in fact all of chemistry may be reduced to the interactions of electrons of one atom with the electrons of another atom.

One of the most important properties that characterizes a substance is its ability to dissolve in various types of liquids. For example, everyone knows that oil and vinegar don't mix--Why is this true? The problem is that vinegar is a "polar" substance, which means that each molecule acts like a tiny magnet. All these magnet-like molecules attract and repel one another, and line themselves up. Water is polar, so other polar substances will dissolve in it rather easily. When one attempts to mix a non-polar substance such as oil in water, it does not work because it is difficult to get the water molecules to separate to let the oil molecules in between them. There are different degrees of polarity and non-polarity, so it is often possible to get two substances which will dissolve temporarily, and then separate later as the polar molecules slowly attract one another, as is the case with most salad dressings. If one chooses the ingredients correctly, and mixes properly, the ingredients will stay dissolved.

Physiological Description

There are three major ways toxic substances can enter the body: through the skin, lungs, or digestive tract. A specific toxic substance may enter the body and do damage through one route, say the digestive tract, but may be unable to enter by another route, say the skin. It is useful to have some understanding of how and why toxic substances are able to penetrate the barriers which attempt to keep the body separate from the outside world.

If a toxic substance is present in a very high concentration - and the body has the ability to sense its presence - one of several mechanisms may come into play to help reduce exposure. The taste buds may reject the substance and motivate the person not to swallow - or if the substance has been swallowed, the esophagus may be activated to perform the vomit reflex - which is basically a long swallow in reverse. Unfortunately, however, many toxic substances do not stimulate either of these responses - and the food is consumed without any immediate problems. As the toxic substance passes through the digestive tract, one of several things happens to it. In some cases the toxic substance may be unable to pass through the walls of the intestine - and so the toxic substance is carried along, and ultimately is eliminated with the feces. In this case there probably is no harm to the body, though it may irritate and cause problems such as cancer in the lining of the stomach, intestine, or rectum.

If the toxic substance in the food or water is able to pass through the wall of the intestine, there is the potential for greater harm. As substances pass through this wall, they enter the blood system, and are carried to the liver. The liver may be visualized as an active filter system which has the ability to alter some substances in such a way that they become either more useful or less harmful to the body. A good example is the ability of some enzymes in the liver to isolate and remove certain heavy metals. Unfortunately, the liver's intricate system is neither perfect nor fool-proof; some toxic substances are not deactivated by the liver, and some are even rendered more toxic by the liver.

After passing through the liver, the blood enters general circulation - going to all parts of the body. It is at this stage that the most widespread damage is possible, as chemicals travel through the bones, nerves, glands, fat, muscle, and other tissues. As previously mentioned the toxics will tend to accumulate in areas depending on their specific chemical properties. Ultimately, the blood passes through the kidneys and here many toxics which have not been absorbed by other tissues are removed from the blood. The kidneys are not perfect, they cannot remove **all** toxic substances, and, of course, since the kidneys remove the toxics they tend to be exposed to the highest concentrations. This can lead to problems with the kidneys themselves, or other parts of the urinary system.

Ingestion of toxic substances may result from various kinds of exposure. The toxic substances may be in the food we eat, water we drink, or even in the air we breathe. The mucous which protects the lungs by trapping and holding many inhaled particles is gradually moved up the wind-pipe and is swallowed. Thus many of the toxic substances in the air will find their way into the digestive tract by riding on dust particles. The body is equipped to handle many of these substances, but many more are not stopped and enter the blood system, thereby gaining access to the entire body.

As we breathe, air enters through the nose, passes through the nasal cavities, on into the windpipe, and finally deep into the passageways of the lungs. At each point along the way there are 'filters' to help to keep out dust and particles. The nose hairs trap the largest airborne particles - frequently causing a tickling sensation which causes us to "back-flush" the system - to sneeze. Particles which are small enough to get by the hair without triggering a sneeze may be trapped in the mucous which lines the sinuses and windpipe. This mucous moves constantly toward the esophagus (gullet) and is unconciously swallowed. (Interesting to note here that by this system some airborne toxics may become ingested toxics.) Particles which are not stopped by the mucuous layers pass deeper into the lungs.

The job that the lungs must perform - 24 hours a day - is to allow oxygen to dissolve from the air into the blood, and to let carbon dioxide dissolve from the blood into the air. This is done by bringing the air and the blood into close contact, in tiny sacks in the lung called aveoli. It is important to note that the aveoli do **not** expand and contract with each breath - they merely open onto passageways in which the air is moving.

The danger lies in that there is a range of sizes of particles which are small enough to get past all of the filters, and yet too big to dirft in and out of most aveoli without making contact and sticking to the aveolar wall. The problem is made more complex by the fact that very small particles, such as individual molecules of some volatile toxic substances, may pass across the membrane which allows the oxygen/carbon dioxide exchange between air and blood, thus entering the bloodstream directly (note that in this case the blood does **not** go directly through the liver, and so there is reduced opportunity for that organ to remove or deactivate toxics). It is also possible that the particles may adhere to molecules of airborne toxics, and thus transfer the toxics more efficiently to the lungs.

ECOLOGICAL DESCRIPTION

Life means recycling. Everything that is, or was, or could be a part of any living thing is part of a grand recycling scheme. The entire recycling process of nature can be broken

down into two broad categories of events; growth, and decomposition. Growth is characterized by substances being brought together from less concentrated sources - such as the bringing together of parts of the soil, air and water for the new leaves of Spring. Decomposition is just the opposite; substances move from a concentrated, organized form into a disorganized, more disperse form, such as the decay and 'disappearance' of the leaves each Autumn. As toxic substances enter the environment, they also undergo these same interactions of increase and decrease in concentration.

DISPUTE RESOLUTION CONFERENCE

Responsible public decisionmaking in a free and democratic society necessarily requires that the public be furnished the best available information in a form that can be understood and used. Science and scientists thus have an obligation to furnish the public their best possible judgments with regard to scientific issues. Scientists are aware that the public's perception of risk varies with the nature of the hazard. For example, the loss of life in a single airplane crash is perceived differently than an equivalent loss of life from auto accidents on a holiday weekend. Science cannot make judgments for society, but science can provide the information that permits more informed judgments. (1,12,13,14,15,16).

To this point, science has not been able to furnish the traditional scientific consensus for decisionmakers, because the necessary data for such a traditional consensus are not yet available. The unfortunate but unavoidable alternative has been to furnish scientific conclusions produced in the context of the "adversarial" framework. This means that the advocates of opposing interests each present their data and their conslusions in an effort to "win" for the result they seek. The public recognizes such contentions as adversarial ones. It is unable to evaluate the complex evidence furnished, but has nowhere to turn for independent scientific judgment. To this point, the result has been loss of credibility, disaffection, and growing concern about whether our societal institutions are adequate.

For this Dispute Resolution Conference, 59 independent scientists have assembled here from throughout the free world, and 50 observers have watched and commented. They have been able to arrive at consensus with regard to most of the important and controversial issues that have been addressed in this conference. They believe that their pilot effort in developing an effective dispute resolution mechanism represents a contribution to the process by which our society may come to judgments with regard to scientific matters.

The convenors of this conference have long believed that our methods for resolving socio-scientific disputes are inadequate, and that new methods of dispute resolution must be developed and

tested. Academic intellectual pursuit is not enough. A specific, controversial subject of dispute, which has not responded satisfactorily to existing mechanisms, was chosen as the conference topic. It provides almost the perfect model. It has been in bitter controversy for well over a decade. It has been the subject of recurrent scientific advisory committees, legislative, regulatory, executive, administrative and judicial action on state, federal and local levels -- more than any other single discrete product. Little seems to have escaped repeated trial as a dispute resolution mechanism, to this point with little success in achieving satisfactory resolution.

2,4,5-T first came to active public consciousness as a result of its use as a defoliant in Vietnam. The early concern with regard to its potential harmful effects was colored by the acrimony and bitterness of our Vietnam involvement. In 1969 the discovery of TCDD, a highly toxic contaminant in 2,4,5-T came to the fore. As Vietnam faded into the background, other concerns about carcinogenicity and teratogenicity maintained high public interest. Books, feature news articles, national television specials and other continuing publicity recently focused public concern on the possibility that 2,4,5-T caused abortions (Alsea, Oregon) and a variety of ills, including cancer, to veterans of the Vietnam conflict.

The scientific dispute resolution mechanism proposed and tested in the past three days was one which would bring together

qualified scientists throughout the world who had information or expertise with regard to 2,4,5-T issues. The purpose was to see whether in the presence of each other, after being furnished the plethora of available information, after freely exchanging data and their interpretations of it, and after examining conflicting views, these scientists could arrive at a consensus with respect to the available data. To ensure credibility, this was to be done in the presence of "observers" from parties at interest, from the media, and from the public.

No one was to be compensated for this public interest effort. But at the same time, clearly the expenses involved would be significant. Not only must scientists be brought from all over the world, but accommodations must be furnished for meetings, and provision made for a variety of the other support services without which a scientific meeting would be impossible.

The Research Foundation of the American Bureau Federation, using member and industry contributed funds, provided the financial support for the conference. One of the critical key conditions of accepting financial support at the inception and throughout, has been that there be no effort to influence the conference procedures employed, or the selection of participants. There has been no such influence.

Using this model, invitations were extended to known interested persons or organizations in government, academia, industry, and environment and consumer groups, and to foreign scientists

who had been involved in aspects of the relevant scientific inquiries.

It is testimony to the dedication of scientists to the public interest and their conviction that something new is needed, that the response was immediate and constructive. Forty-eight scientists attended from 20 states of this nation, as well as 11 from the nations of New Zealand, Switzerland, Italy, Germany, France, Sweden and Canada. Many came because an effort was underway to test a new mechanism for resolving important socio-scientific problems.

In addition to these scientists, 50 observers attended, from government, academia, environmental organizations, industry, the media, and even the U.S.S.R. Attachments A and B list the scientific participants and public observers, identifying residence and institutional affiliation.

We believe that the Conference has had before it the significant data, research results, opinions, and other information presently available with respect to the critical issues regarding the herbicide 2,4,5-T and the contaminant TCDD. As scientists, we know that there is more work to be done. We know that tomorrow new information may modify our present judgments and conclusions. As scientists, we would far prefer to be able to wait until tomorrow before we express our scientific views. As members of society, however, we know that we cannot wait until then.

We have an obligation to let the public know today of our conclusions based on evidence available, so that they may come to decisions for themselves.

MAJOR CONCLUSIONS OF THE WORKSHOPS:

Carcinogencity - Mutagenicity

"2,4,5-T is not a carcinogen nor mutagen in animal test systems studied to date.

TCDD[2] is carcinogenic for rats and mice.

TCDD is a mutagen in two bacterial reverse mutation systems, but no in vivo correlates of mutagenicity have been found.

Phenoxy herbicides containing TCDD have not been shown to be carcinogenic in humans in retrospective edidemiologic studies to date.

Based upon the most definite animal carcinogensis study, the working group felt that extrapolation from the high dosages of the test chemical should be made to dosages that might possibly be encountered in the environment during continuous lifetime exposure."

Teratogenicity

Effect of 2,4,5-T on Reproductive Parameters in Animals:

"A review of early studies in animals revealed that high doses of 2,4,5-T containing 0.1 ppm of TCDD or less produced cleft palate (mouse only) or embryo lethality in a number of

experimental species (mouse, rat, hamster, sheep, monkey, rabbit). A recent three-generation reproduction study in rats was available for examination by this group. Neonatal survival was decreased in a dose-related manner, and the no-adverse-effect dose level in the species most sensitive to 2,4,5-T, the mouse, was 20 mg/kg/day.

Effect of TCDD in Reproductive Parameters in Animals:

Studies in rats and mice for teratogenic and embryo-toxic effects revealed the highest no-effect dose level in rats to be 0.03 u g/kg/day (teratogenicity). At higher doses, cleft palates, intestinal hemorrhage, kidney changes, or embryofetal lethality was observed.

In studies conducted in rats and monkeys, the apparent no-effect level in rats was 0.001 u g/kg/day, a level of 10X below the demonstrated no-effect level in Rhesus monkeys.

Effects of 2,4,5-T and TCDD on Reproductive Parameters in Humans:

Alsea Study--The miscarriages reported in this study were not demonstrated to result from the spraying of the forests with 2,4,5-T.

Analysis of available data[1] leads this group to the conclusion that no adverse effects on human reproduction have yet been demonstrated after exposure to 2,4,5-T or TCDD."

Human Exposure

"Sufficient evidence exists to date to conclude that chloracne in humans is the most frequently manifested consequence of exposures to TCDD and may occur without other evidence of toxicity.

The group found no evidence for an abortifacient effect of TCDD in the human.

The group considered the Alsea, Oregon data and reached a consensus that such serious deficiencies existed in the data that no conclusions were possible regarding possible abortifacient effects of 2,4,5-T.

In regards to the data on TCDD exposure in Seveso, the group concluded that evidence of no manifest teratogenic effect in Seveso over the time period of observation exists.

The group concluded that there was no evidence of an association between birth defects of the neural tube and exposure to 2,4,5-T in either the New Zealand or Victoria, Australia investigations.

The group agreed that the available data cannot be interpreted as providing either positive or negative evidence of a carcinogenic effect in the human.

TCDD was not found in the urine of personnel who applied 2,4,5-T sprays in the forest. Based on a TCDD concentration of

0.04 ppm in the formulated product, 2.9 x 10^{-6} u g/kg/work day is the maximum amount that could have been absorbed."

Ecological Effects

"2,4,5-T itself, relative to TCDD as a contaminant, is of minimal ecological concern subject to several qualifications as to conditions of use.

TCDD degrades rapidly on leaves, in water, and on the soil surface through the action of sunlight. However, once incorporated in soil, measured half-lives have ranged from 1 to 3 years or more.

In terms of levels of TCDD entering the top few inches of soil, routine right-of-way applications in the United States represent about 1/13,000th the level of contamination that was initially associated with the Seveso, Italy episode, and about 1/1000th of that currently remaining from 2,4,5-T applications (experimental equipment calibration) at Eglin Air Force base in Florida about 15 years ago.

The highest environmental residues of TCDD from approved 2,4,5-T application that can currently be documented (based on a single sample) is 60 ppt in one beef fat sample.

Although the available analytical data provide little evidence that TCDD is accumulating in the environment as a result of normal domestic use of 2,4,5-T, larger numbers of samples must be analyzed with even more specific methods before this can be established.

The major area of uncertainty concerns the questions of whether such levels could be expected to result in detectable (immediate or delayed) biological effects. Although no known biological effects in connection with routine 2,4,5-T use have been documented over a 30 year period, we cannot say with total assurance that such effects cannot, do not, and will not occur.

Chemistry

"It was agreed that no levels of TCDD in the ppm or ppb range have been detected in the environment exclusive of waste disposal or spills. It was further agreed that levels at 100 ppt or above have not been detected in any environmental sample associated with the normal use of 2,4,5-T, i.e., fish, beef or mothers' milk. Below this level, specific substrates and studies must be considered separately:

Mothers Milk--Based on three separate studies conducted up to January, 1979, no validated TCDD residues above 1 ppt have been detected based on analyses of 44 mothers' milk samples. There are no confirmed[1] detected levels of TCDD in mothers' milk.

Beef Fat--Out of 85 samples (including 20 controls) there was only one sample of beef fat confirmed at 60 ppt of TCDD and two apparent but unconfirmed samples at 20 ppt. The remainder of the samples were below the detection limits of 10 ppt. These data were obtained from the EPA "Dioxin Implementation Plan."

In a separate published study in 1976 by one laboratory, 24 samples of beef fat from animals known to have grazed on 2,4,5-T treated forage were analyzed at a level of sensitivity of 6 ppt. None of the samples showed a residue of TCDD at or above the limit of detection[2].

Beef Liver--Of the 43 beef liver samples from cattle grazed on 2,4,5-T treated rangeland (EPA "Dioxin implementation Plan"), no confirmed TCDD residues were present at a level of sensitivity of 4-8 ppt.

Bovine Milk--One laboratory has reported in the scientific literature a study based on work done in 1974 with lactating cows grazed on 2,4,5-T treated foliage. No milk sample from these animals showed a residue of TCDD above the detection limit of 1 ppt.

Fish--A published scientific report on the analyses for TCDD in fish taken from waters adjacent to areas of regular 2,4,5-T use (in Arkansas and Texas) in 1975 showed no detectable TCDD at a sensitivity of 10 ppt.

Wildlife--In connection with normal patterns of use of 2,4,5-T, few studies of TCDD residues in wildlife have been done. The largest study used inadequate analytical methodology and did not yield sound quantitative data. A later unconfirmed small study did not detect TCDD in livers of a large native rodent species collected in forest spray area.

Environment--Is 2,4,5-T the sole source of 2,3,7,8-TCDD in the environment? No. There are other sources such as combustion of certain chlorinated organic compounds whether in industrial or municipal waste. There are indications that other combustion sources are implicated as well. It is impractical to attempt to eliminate all of these sources at the present time.

Concern has been expressed regarding the persistence of 2,4,5-T and TCDD in the environment. Extensive studies with 2,4,5-T over many years have shown it to break down quite readily. The half-life of 2,4,5-T in soil at normal rates of application will range from two weeks to four months. Temperature, moisture, fertility, and soil type may modify the rate of disappearance, but the half-life of 2,4,5-T rarely exceeds four months.

TCDD, on the other hand, while rapidly degraded by light, appears much more persistent in soil and aquatic systems. At the extremely low concentration that would accompany the normal application of 2,4,5-T, it is probable that the half-life is not in excess of one year. However, in laboratory experiments or chemical accidents where greater amounts have gotten into the soil, the half-life appears to be significantly longer. One possible explanation of this is that the biological activity of TCDD is so high that at saturation concentrations in soil solutions, the chemical or biological mechanism responsible for its disappearance is inhibited, thus resulting in longer persistence."

Benefits

"Given the data available, the majority of the work group concurred with the conclusion that significant economic losses would occur if 2,4,5-T were not available for use in forestry. Higher costs would occur in the control of brush in rights-of-way and losses in production from pasture and range would result. Given current production practices, losses would be sustained in rice production. However, several members questioned the extent of the rice production losses because of lack of documentation of data and assumptions.

PRODUCT PERFORMANCE REQUIREMENTS

Guidelines on product performance for herbicide registration serve two major purposes: protection of the environment and assurance of consumer benefit to purchasers and users of pesticide products. (5,12,16). Environmental protection would be achieved by making certain that applications of pesticides are fully and adequately effective for their intended purposes, so that:

(1) Undue pollution of the environment (and the consequent environmental exposure) does not result from the use of:

(a) Ineffective products or ineffective active ingredients;

(b) Excessive or insufficient amounts and rates of pesticides to achieve the desired effects;

(c) Excessive or insufficient frequency of pesticide applications;

(d) Inappropriate timing of applications, as, for example, too early or too late, or out of season; and

(e) Impractical product mixtures containing certain active ingredients that get heavy usage because of other ingredients, but are rarely if ever needed themselves under most pest control circumstances.

(2) The time, labor, equipment, and energy needed to achieve the desired effect are most efficiently used; this concurrently constitutes a major benefit toward improved safety for both humans and the environment, since reduced opportunity then exists for accidents, needless exposures, bioaccumulation, and other similar hazards.

Consumers would benefit because certain label claims are meaningful and truthful, and that the product label instructions are relevant and practical for safe and effective use of each product determining that:

(1) Label claims for control of pests or specific plant/animal responses are verified by scientific evidence;

(2) Label directions for use are consistent with commonly-recognized practices of pesticide use; and

(3) Label directions for use are supported by scientific evidence based on testing of the pesticide under use conditions consistent with label directions.

Recommended methods for satisfying data requirements as well as supplemental recommendations for expanding methods for specific claims and use patterns, are necessary.

Efficacy of Aquatic Plant Control Agents, would include data requirements on herbicides used in aquatic environments.

Performance Standards. Many of the individual sections must contain performance standards. A performance standard would represent the lowest level of product performance which would normally be acceptable for registration purposes for a specific site and pest combination. The proposed performance standards are usually expressed as percentages of pest control. Performance deviating greatly from these proposed standards might prompt the Agency to require lesser label claims (when such reduced claims can be tolerated), or extensive additional information on benefits or on adverse effects from higher dosages.

Effectiveness. Each section must descripe the criteria used to determine the effectiveness of the product in preventing destroying, repelling, or mitigating a pest; accelerating or retarding the rate of growth of a plant or otherwise altering the behavior of the plant or defoliating plants or artifically accelerating the drying of plant tissues. Effectiveness would be determined by experiments that satisfy the performance standards. Adverse effects and hazards to man and the environment would be discussed. In addition to the adverse effects specifically evaluated, these guidelines would require evaluations of other

kinds of adverse effects such as deteriorated food, quality, discolored and weakened fabrics, unsightly residues on plant foliage, reduced crop palatability, increase in harmful nontarget organisms, and presence of dead pest organisms as a potential food source for domestic or wild nontarget organisms.

WAIVER OF DATA REQUIREMENTS PERTAINING TO EFFICACY

A recent amendment to section 3(c)(5) of the FIFRA provides that the Administrator may waive data requirements pertaining to efficacy. EPA in testimony before Congress, stated that it is most concerned about ensuring a product's effectiveness when a lack of efficacy could result in adverse human health effects. In keeping with this concern, the Administrator has deemed that all products not having a direct impact on public health may have their efficacy requirements waived. However, under certain conditions (such as when pesticides are under cancellation or suspension, or under rebuttable presumption against cancellation), efficacy data would be required.

"Section 3(c)(5) of the FIFRA provides that the Administrator may waive data requirements pertaining to efficacy of a product under consideration for registration, and that if he waives the requirement for data, he may also waive the finding of efficacy required by FIFRA section 3(c)(5)(A). Since efficacy data waiver is a major deregulation action, EPA will consider the waiver policy enunciated in these regulations as an experiment in

public policy. If there is sufficient evidence to clearly establish that this deregulation is being abused (such as a significant increase in complaints from the agricultural community, other user groups, or the general public about ineffective products, the Administrator may take any steps necessary to correct the abuses, including withdrawal of any or all waivers of efficacy data requirements.

"The decision to pursue efficacy waiver as an EPA policy stemmed from a need to reduce the amount of resources devoted to reviewing product performance so that additional effort could be devoted to the evaluation of health and safety data, and from a desire to reduce regulatory burdens in pesticide registration. Data review obligations placed on the EPA by the requirements for registration were important factors influencing the decision. Maintenance of a rigorous efficacy data submission and review posture for registration and reregistration would require the reevaluation of much of the 1.5 million items of product performance data that have been amassed by the EPA. Because many of these studies are quite old, their value as tools for assessing current levels of products performance is questionable in many cases. Therefore, commitment of the resources needed to fully evalutate these data for purposes of reregistration was determined to be less than an ideal use of limited resources for pesticide regulation.

"EPA's" viewpoint concerning waiver of efficacy data requirements is in line with a general belief among persons in the pesticide industry, the U.S. Department of Agriculture and the agricultural community that the efficacy of agricultural pesticides can be effectively regulated by the marketplace (in conjunction with extension services and university research personnel). This opinion has subsequently received some qualified support from the findings of A.D. Little Inc. (Draft Report: Evaluation Design for a Change in the Pesticide Regulatory Process: The Waiver of Efficacy Data). As originally proposed in the draft Conditional Registration regulation of October 6, 1978, the efficacy waiver was to apply to all product uses except for those termed "public health uses." These public health uses were restricted to certain disinfectant uses and a limited number of vertebrate and invertebrate control agents aimed at potential disease vectors such as bats, rats, and mosquitoes. The proposal of efficacy data waiver generated a mixed response from commenters. The pesticide industry was generally supportive of the concept of efficacy waiver. On the other hand, comments from State researchers and Cooperative Extension Service personnel expressed reservations about various facets of the proposed waiver. Many commenters expressed concern over the extent of efficacy waiver, arguing that the scope of "public health" uses should be greater than that proposed. The efficacy data requirement contained in section 162.18-2 retains the concept of public health uses, but has clarified and expanded

public health uses to include additional disinfectant, rodenticide and insecticide uses, and one fungicide use.

"Some commenters expressed the belief that waiver of efficacy data requirements will signal an open season to unscrupulous "fly-by-night" operators who will defraud the public by marketing ineffective products, or products with exaggerated or unwarranted efficacy claims on labeling and in advertising. Undoubtedly, there will be instances in which the marketplace will fail to operate as expected. EPA believes that foreseable imperfections in mareketplace self-regulation are acceptable tradeoffs in return for a reduction of overall Federal regulation in the efficacy area.

"EPA, in cooperation with the Experimental Technology Incentives Program of the National Bureau of Standards will monitor the impacts of the efficacy waiver policy to determine if:

"(1) Consumer fraud increase[s]; or

"(2) Consumer fraud is effectively reported and curtailed through existing market institutions including State regulation processes, USDA and the Extension Service, farmers associations, and the marketplace. EPA expects that all registrants will perform the tasks necessary to assure themselves that the products the market will perform their intended functions when applied in accordance with label directions and commonly accepted pest control practices. The Agency must rely upon the integrity of the

industry, the soundness of extension service recommendations and the good judgment of pesticide users to insure that abuses seldom occur. The Administrator reserves the right to request submission of efficacy data in support of label claims for any registered product. A request may be made for any product for which a pattern of inadequate performance has been reported.

"Some respondents feared that efficacy data waivers would lead to a lack of sound information on the "benefits" side of the risk/benefit analyses performed as part of the Rebuttable Presumption Against Registration (RPAR) or cancellation processes. Benefits analysis in the RPAR process entails substantially more than reconsideration of efficacy data supporting the original registration. Concern in the benefits analysis is not with historical but with current product performance. In addition, economic factors pertaining to the current use of the pesticide and efficacy of alternative chemicals or non-chemical control practices must be considered. Front-end efficacy review does not provide useful information on the suitability of alternatives. However, when a substantial risk of unreasonable adverse effects has been identified via the RPAR or cancellation/suspension processes for old use patterns of a pesticide, it is incumbent upon the Agency to more carefully scrutinize new or added uses of the pesticide, weighing those risks with the benefits they offer. Thus, the waiver policy has been amended to include a requirement for efficacy data for new or added uses of products which have been RPAR'd, cancelled or

suspended for adverse effects of other uses, if the identified adverse effects would also be expected to occur with the new or added use.

TEST STANDARDS

Test substance. Final tests to support the effectiveness of a product would usually be conducted with the formulation proposed for registration and frequently with the product in the same packaging intended to be used commercially. This latter requirement would be especially important in case of pesticides marketed and applied directly from containers or container-devices. Tests using the formulated product would be required because formulated products found to be effective in laboratory tests may sometimes be ineffective when packaged in commercial quantities for a variety of reasons, including synergism, antagonism, physical incompatibility with inerts, short shelf-life, chemical reaction with a component added at repackaging, or improper functioning of containers which also serve as application devices. Moreover, a product initially effective at the user level may suddenly become ineffective or unusable because of a change in the can liner coating, product emulsifier, solvent, or other component used. Mixtures of two or more pesticides in a single formulation may react chemically, be physically incompatible (producing a useless product), or be mutually antagonistic or synergistic for effectiveness or adverse effects.

Minimum Effective Dose (MED) and Effective Dosage Range (EDR). General Requirements, paragraph (b)(3) would require the applicant to demonstrate the minimum effective dose and the effective dosage range. These data would be useful in risk/benefit considerations where a determination of lower dosage rates may, in some cases, allow a reduction in adverse effects or environmental contamination while still providing acceptable levels of pest control.

Performance Standards. The product performance guidelines would establish specific performance standards for several different areas. These standards would benefit the EPA and the consumer because they would ensure that the products are useful and will control the pests indicated on labeling. They have been discussed extensively and are considered to represent suitable standards at this time. Many of the performance standards have been routinely used by the Agency for years. In some instances, experts throughout the country were contacted to develop some of the performance standards, as well as the Agency's own scientists at headquarters and at laboratories and field stations. Performance standards will be revised from time to time when deemed necessary by the EPA.

Some of the performance standards are based on comparisons of the effectiveness of products to the effectiveness of standard reference chemicals. Often the performance standards are very explicit as to whether the comparison involves the amount of

chemical/acre, reduction in pest/acre, different target pest, or adverse effects to the crop.

SUMMARY AND CONCLUSIONS

One can conclude that pesticide laws and common law principles applicable to the use of pesticides do a reasonably adequate job of protecting the public. The development of further regulation by way of statutes and rules is necessary in some instances before adequate, useful and practical means are made available, thus minimizing pesticide accidents. Statutory control should not only regulate, restrict and likewise even make lawful certain acts and procedures, but also, pesticide laws should serve as educational tools to inform and delineate proper activities of users, sellers and applicators.

Statutes which merely prohibit, do serve a useful purpose. However, in the case of a law limiting activities of individuals, while the reasons for the limits may be obvious to law makers, this is not always the case with the affected or regulated parties. Statutory language, while not necessarily explanatory per se, should be detailed enough to point out the proper means of compliance.

It will no doubt take years of hard work on a number of fronts to obtain relatively uniform and comprehensive pesticide labeling, use and certification law. Liberal access to the courts and favorable decisions for plaintiffs indicate a fertile

area for extension of present common law remedies. Therefore, if any legal action, or even more, the initial injuries to persons and property by the sale or use of pesticides, can be avoided by increased statutory control. Not that we need or wish to over-legislate, only that we must confront the pesticide legal problem intelligently and vigorously.

The program for restricted use pesticides and certification of applications as established under the current law for registration of pesticides, including herbicides, has generally succeeded.

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